

We claim:

1. A method comprising retaining a reservoir for a therapeutic agent between the scalp and cranium of a subject.
2. A method according to claim 1 wherein the reservoir is hermetically sealed with a metal.
3. A method according to claim 2 wherein the metal is a foil.
4. A method according to claim 1 further wherein the reservoir comprises one or more bladders adapted to occupy a substantially planar space between the scalp and cranium.
5. A method according to claim 4 further wherein there is more than one bladder and the bladders are connected with at least one fluid conduit allowing therapeutic agent to flow from one bladder to the other.
6. A method according to claim 1 further including refilling the reservoir using a hypodermic needle that is inserted through the scalp and into a refill port on the reservoir adapted to receive the needle.
7. A method according to claim 6 wherein the reservoir is substantially planar, and the port is oriented so that the needle is inserted along a line that is generally parallel to the plane of the reservoir.
8. A method according to claim 6 wherein the reservoir is substantially planar, and the port is oriented so that the needle is inserted along a line that is generally perpendicular to the plane of the reservoir.

9. A method according to claim 1 wherein the reservoir is substantially planar, and the edges of the housing of the reservoir taper from a smaller thickness at the edge to a greater thickness away from the edge.

10. A method according to claim 1 further including deploying the reservoir in the space between the scalp and cranium using one or more deployment lines connected at or near the edge of the reservoir that when pulled deploy the reservoir in a desired position.

11. A method according to claim 1 including one or more additional reservoirs holding one or more different therapeutic agents.

12. A method according to claim 1 including retaining the reservoir subcutaneously between the subject's scalp and cranium so that the reservoir outline is imperceptible to a casual observer.

13. A method according to claim 1 further including anchoring the reservoir by suturing to the subject's galia.

14. A method according to claim 1 further wherein the reservoir is a pouch that is held dimensionally fixed on all axes except one.

15. A method according to claim 14 further wherein the reservoir is formed at least in part with a silicone or polymer.

16. A method according to claim 1 wherein the reservoir is a pouch, and when the reservoir is full, the pouch is confined by a solid surface such as the inside of an outer hermetic enclosure or a molded plastic restrainer.

17. A method according to claim 2 further wherein one end of the reservoir has a fixed dimension and contains an outlet port and a filling port, with the opposing end having a non-fixed dimension and is activated by a push rod or piston mechanism to predictably collapse the pouch while pushing the therapeutic agent out under constant pressure.
18. A method according to claim 17 wherein a screw or impeller pump is located at the fixed end of the reservoir and withdraws the agent from the reservoir.
19. A method according to claim 2 wherein the reservoir is a pouch and the agent is pumped from the pouch, and the pouch collapses as it is emptied, maintaining the appropriate pressure/volume ratio inside the pouch and thereby preventing air from entering the pouch.
20. A method according to claim 1 wherein the reservoir is a solid cylinder with the outlet port or valve mechanism located on one end of the cylinder, and the opposing end is fitted with a push rod/sealing piston to retain the therapeutic agent and to force the therapeutic agent through the outlet port.
21. A method according to claim 20 further wherein after an infusion cycle, the drive or stepper motor reverses enough to release pressure on the therapeutic agent chamber and to maintain a neutral or slight negative pressure in relation to that of the surrounding anatomy.
22. A method according to claim 2 wherein the reservoir is a square or round hollow, rigid tube coiled to maintain a flat or specifically shaped profile of minimum surface area, and the reservoir is filled through an inflow valve located at or near one end of the tube, and the outflow port is located at the opposite end of the tube from the filling port.

23. A method according to claim 2 further wherein the reservoir is a collection of multiple reservoirs, connected by tubing, designed to provide a flexible or contoured implant device shape that can form to the shape of subject's skull, and wherein the reservoir is filled by syringe through a fill port attached to one of the reservoir sections and thereby fills all reservoir sections through the connected tubing.
24. A method according to claim 23 further including a pump located in a manner that provide complete drainage of all reservoir sections during a therapy cycle.
25. A method according to claim 2 wherein refill of the reservoir is accomplished through a sealed silicone portal that is accessed by a needle through the skin.
26. A method according to claim 1 wherein the reservoir is of a shape substantially that of the top of a human head.
27. A method according to claim 1 further including dispensing the therapeutic agent from the reservoir to a location in the brain of the subject.
28. A method according to claim 1 further including dispensing therapeutic agent from the reservoir to a treatment site in the spine of the subject.
29. A method according to claim 27 further including dispensing the therapeutic agent based on programmed parameters.
30. A method according to claim 27 further including dispensing the therapeutic agent based on signals telemetered transcutaneously.

31. A method according to claim 27 including telemetering dispensing information transcutaneously to a device outside the subject's body.
32. A method according to claim 27 including dispensing the agent with a fluid conduit with a proximal end coupled to receive agent from the reservoir and a distal end positioned in the brain of the subject.
33. A method according to claim 28 including dispensing the agent with a fluid conduit with a proximal end coupled to receive agent from the reservoir and a distal end positioned in or proximate the spine of the subject.
34. A method according to claim 1 further including dispensing a variable dosage of therapeutic agent from the reservoir to a treatment site.
35. A method according to claim 1 further including dispensing a timed dosage of therapeutic agent from the reservoir.
36. A method according to claim 27 wherein the agent is dispensed by pumping it to the location in the subject's body with a pump, the pump is a diaphragm pump or piston pump that controls dosage volume by change in volume per stroke X number of strokes, and further including controlling the flow of agent using a first valve to regulate the inflow and a second valve to regulate the outflow wherein the inflow valve is a mechanical valve displaced by the refill needle.

37. A method according to claim 27 wherein the agent is dispensed by pumping it to the location in the subject's body with a pump, the pump is a diaphragm pump or piston pump that controls dosage volume by change in volume per stroke X number of strokes, and further including controlling the flow of agent using a first valve to regulate the inflow and a second valve to regulate the outflow wherein the inflow valve is an electronically controlled valve that is activated by an external device at the time of filling.

38. A method according to claim 27 wherein the agent is dispensed by pumping it to the location in the subject's body with a pump, the pump is a diaphragm pump or piston pump that controls dosage volume by change in volume per stroke X number of strokes, and further including controlling the flow of agent using a first valve to regulate the inflow and a second valve to regulate the outflow wherein the outflow valve is electronically controlled and timed to the outflow cycle of the pump.

39. A method according to claim 27 wherein the agent is dispensed by pumping it to the location in the subject's body with a pump, the pump is a diaphragm pump or piston pump that controls dosage volume by change in volume per stroke X number of strokes, and further including controlling the flow of agent using a first valve to regulate the inflow and a second valve to regulate the outflow wherein the outflow valve is a normally closed valve located at the distal end of a catheter carrying the therapeutic agent to the location in the subject's body, and when therapeutic agent delivery is required, the valve is electrically opened and remains open for a programmed period of time.

40. A method according to claim 39 further wherein conductors for the valve are embedded in the sidewall of the catheter.

41. A method according to claim 27 wherein the agent is dispensed by pumping it to the location in the subject's body with a pump and further including retaining an implanted power source within the subject's body wherein the power source powers the pump.

42. A method according to claim 41 wherein power source is rechargeable.

43. A method according to claim 42 wherein power source is rechargeable battery or storage capacitor.

44. A method according to claim 43 wherein the power source is integral with electronic circuitry used to control the pump.

45. A method according to 42 including transcutaneously transmitting power to the power source to recharge the power source.

46. A method according to claim 42 further including pumping the therapeutic agent as an external power source is placed over the site of the pump.

47. A method according to claim 42 further including forming at least one cavity in the cranium of the subject, and placing at least a portion of the power source in the cavity.

48. A method according to claim 27 wherein the agent is dispensed by pumping it to the location in the subject's body with a pump and further including positioning the power source inside the body of the subject at a location other than the top of the head of the subject.

49. A method according to claim 27 wherein the agent is dispensed by pumping it to the location in the subject's body with a pump and further including positioning the power source under the skin behind the ear of the subject.

50. A method according to claim 27 wherein the agent is dispensed by pumping it to the location in the subject's body with a pump and further including positioning the power source in the chest region of the subject.

51. A method according to claim 1 further including one or more electronic components adapted to control the dispensing of therapeutic agent from the reservoir to the subject's body and containing the electronic components or pump in a hermetically sealed container suitable for long term human implant.

52. A method according to claim 51 wherein the container is constructed of one or more materials from the following group: titanium and stainless steel.

53. A method according to claim 1 further including forming at least two cavities in the cranium of the subject, and placing at least a portion of a pump in one cavity and at least a portion of a power source for the pump in the other cavity.

54. A method according to claim 27 further including electronic circuitry operating the pump based on programmed parameters and a device external to the subject's body to telemeter signals into and out of the electronic circuitry.

55. A method according to 54 wherein the external device reprograms the electronic circuitry as necessary, and collects and displays data as transmitted from the implantable device.

56. A method according to claim 54 wherein the external device may signal the electronic circuitry to cause an extra dose of therapeutic agent to be delivered upon demand by an operator.



57. A method according to claim 27 further including electronic circuitry operating the pump based on programmed parameters and bidirectionally transmitting signals to activate the circuitry within the implant device and relay status information from the circuitry to outside the subject's body.

58. A method according to claim 57 including starting energy and signal transmission either automatically by proximity of the external device to the implanted device or by a control activated by an operator.

59. A method according to claim 27 further including electronic circuitry operating the pump based on programmed parameters wherein the components are enclosed in a fluid-tight enclosure and all electrical components and connections are hermetically sealed against potential moisture related failures.

60. A method according to claim 27 further including a pump and power source, and further wherein the pump and power source are housed integral to the pump and reservoir.

61. A method according to claim 27 further including a pump and power source, and further wherein the pump or power source are located remotely from the reservoir.

62. A method according to claim 61 further wherein the pump or power source are implanted in the subject's body.

63. A method according to claim 61 wherein single or multiple conductors carry power from the power source to the pump.

64. A method according to claim 63 further including encasing the conductors in a biocompatible flexible material.

65. A method according to claim 64 further wherein the biocompatible material is selected from the group of: silicone or polyurethane and wherein the conductors are permanently attached to the pump and electronic components for controlling the pump in a manner that allows them to be disconnected.